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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,948	09/10/2003	Timothy A. Hovanec	P 0294309 081289	7889

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/659,948	HOVANEK, TIMOTHY A.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 16, 18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16, 18 and 20-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

The amendment filed 6/15/06 is acknowledged. Claims 1-7, 16, 18 and 20-21 are being considered on the merits.

The application should be reviewed for errors. Error occurs, for example, in the recitation "an man-made aquarium" in claims 1 and 18.

The rejection under 35 U.S.C 112 regarding deposit is withdrawn in view of the Lu Declaration.

Claims 1-7, 16, 18 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a alleviating or preventing accumulation of ammonia in certain environments such as a household aquarium containing salt water, does not reasonably provide enablement for the alleviation or prevention of the accumulation of ammonia in any and all environments by providing certain bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and ,
- 8) the relative skill of those skilled in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

- 1) the nature of the invention; the invention is directed broadly to an anti-ammonia process but has not recited the step(s) that (a) result in preventing nor (b) have a specified end result of the treatment.

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2) the breadth of the claims; the scope of the method claims includes the prevention and alleviation of ammonia in all possible environments.

3) the predictability or unpredictability of the art; the ability of preventing and alleviating the accumulation of ammonia in any and all environments appears difficult, if not impossible. It is noted that the method as claimed encompasses the administration of the bacteria to animals such as humans to prevent or alleviate the accumulation of intestinal ammonia, for example. The burden of enabling one skilled in the art to prevent accumulation of ammonia in any and all possible environments, including animals and environments toxic for the bacteria involved would be much greater than that of enabling the alleviation of accumulation in certain specific environments favorable to bacterial growth. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing or alleviating ammonia accumulation in animals or environments such as paper mills, for example. Nor is there any guidance provided as to a specific protocol to be utilized in order to determine the appropriate environment.

The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing and for practicing same without a specific endpoint for the prevention and alleviation of the accumulation of ammonia.

4) the amount of direction or guidance presented; the specification does not provide any guidance in terms of alleviation or prevention of accumulation of ammonia as claimed.

5) the presence or absence of working examples; no working examples are provided for preventing accumulation of ammonia, for example in an animal or human, in the specification. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

6) the quantity of experimentation necessary; the quantity of experimentation would be undue to one of skill in the art and amount to the trial and error type of experimentation without a priori expectation of success. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in

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the instant case for the instant method claims. To support a claim to prevention or the like, Applicant would need to provide confirmative data supporting the prevention ammonia accumulation as well as the circumstances resulting in the prevention of such accumulation.

There is no clear indication on this record that provision of a bacterial strain having at least 96% identity to SEQ ID NO 1 is sufficient to prevent or alleviate ammonia accumulation in any environment. The bacteria are disclosed as being able to exist at concentrations no higher than 5 mg/L ammonia (Example 9) and appear to have been only cultured in a specific mixture of bacterial strains for use in reduction of ammonia concentration rather than *per se*. (Example 11). See also paragraph [0102]. Thus it is not apparent that applicant teach how to use a single strain for the stated purpose in any environment. In addition, it is apparent that bacterial strains having at least 96% identity to SEQ ID NO 1 are salt-requiring, which is not addressed by the claims as written.

In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing and alleviating accumulation of ammonia in any environment by bacteria having at least 96% identity to SEQ ID NO 1, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-6, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

#### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants citation of previously granted patents is not persuasive regarding the prosecution of the present application, since each patent application is prosecuted on its own merits and what was done in a previous case does not constitute imprimatur for the prosecution of further cases. *In re Gyurik*, 596 F.2d 1012, 201 USPQ 552 (CCPA 1979); *In re Attwood*, 267

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F.2d 954, 122 USPQ 378 (CCPA 1959); *In re Freedlander*, 136 F.2d 759, 760, 58 USPQ 402, 403 (CCPA 1943).

While it is true that certain portions of the specification are directed to freshwater or salt water strains, the strains having SEQ ID NO: 1 are used in Example 14 for a seawater aquarium exclusively. Applicant's bald statements regarding embodiments of the invention that oxidize ammonia fresh and salt water in Examples 11-13 are noted. However, this does not indicate with any specificity which of the embodiments in these examples pertain to strains having SEQ ID NO: 1 or strains containing a nucleotide sequence that has at least 96% identity over the full length thereof to SEQ ID NO: 1. It is noted also that these types of bacteria appear to require low ammonia concentrations to be effective.

The general teachings in the specification regarding the abilities of large varieties of strains generally used in undefined mixtures does not provide a clear written disclosure for the use of strains containing a nucleotide sequence that has at least 96% identity over the full length thereof to SEQ ID NO: 1 as claimed under any and all conditions, even though the skill in the art is high.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

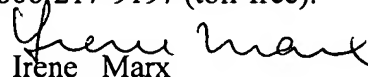
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx

Primary Examiner

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